

DEC 18 2007

510(K) SUMMARY

Creaspine SupStance Vertebral Body Replacement System

Proprietary Name: Creaspine SupStance Vertebral Body Replacement System

Common Name: Spinal Vertebral Body Replacement System

Proposed Regulatory Class: Class II
Spinal intervertebral body fixation orthosis
21 CFR 888.3060

Device Product Code: 87 MQP, Spinal Vertebral Body Replacement Device

For Information Contact: Marc Bernard
Regulatory Affairs Director

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Date Summary Prepared: September 7, 2007

Predicate Devices

The Creaspine SupStance Vertebral Body Replacement System (SupStance VBR System) is substantially equivalent to the following legally marketed spinal vertebral body replacement devices:

- Surgical Titanium Mesh™ System (DePuy-Acromed™, Inc., K003043)
- Surgical Dynamics Mesh Cage System (United States Surgical, K003709)
- Theken Spine Vu Mesh VBR System (Theken Spine, LLC, K070381)

Device Description

The Creaspine SupStance Vertebral Body Replacement System (SupStance VBR System) is a vertebral body replacement system, intended for use as an aid in spinal fusion. The SupStance VBR System consists of the SupStance VBR implant and the associated instrumentation required for implantation of the device. The SupStance VBR

implant is a cage constructed of fused hollow cylindrical tubes with integral endcaps and open sides for introduction of bone graft material and bone reconstruction. The SupStance VBR cages are available in three diameters (22mm, 25mm, 28mm) and cover a range of heights from 35mm to 55mm with a total fixed sagittal angle of 5°.

The SupStance VBR cages are fabricated from poly-ether-ether-ketone (PEEK) and include markers made from titanium alloy. The implants are provided non-sterile and will be implanted via an antero-lateral approach.

Intended Use

The SupStance VBR System is a vertebral body replacement system intended to replace a vertebral body. It is designed for use in the thoraco-lumbar spine (T1- L5) to replace a collapsed, damaged, or unstable vertebral body during tumor or trauma (i.e., fracture) management procedures. The SupStance VBR System is intended to be used with supplemental internal fixation systems. Anterior thoracolumbar plates and screws or pedicle screw and rod systems are among the options for the surgeon to use.

The use of allograft and/or autograft with the SupStance VBR System is optional.

Statement of Technological Comparison

The subject components share the same intended use, basic design concepts, and materials as that of the predicate devices. Performance testing included the types of mechanical testing recommended for vertebral body replacement systems (static and dynamic compression testing, static and dynamic torsion testing, and expulsion testing) in the “FDA Guidance for Industry and FDA Staff, Spinal System 510(k)s” (issued May 3, 2004). The data collected confirms that the mechanical properties of the proposed SupStance VBR System are comparable to those of the predicate devices. The information and data collected support a claim of substantial equivalence for the proposed SupStance VBR System to the specified predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 18 2007

Creaspine SAS
% Medical Device Consultants, Inc.
Cynthia J.M. Nolte, Ph.D., RAC
Senior Regulatory Consultant
49 Plaine Street
North Attleboro, MA 02760

Re: K072537

Trade/Device Name: Creaspine SubStance Vertebral Body Replacement System
Regulation Number: 21 CFR 888.3060
Regulation Names: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: November 9, 2007
Received: November 18, 2007

Dear Dr. Nolte:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a long horizontal flourish extending to the right.

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K072537

Device Name: Creaspine SupStance Vertebral Body Replacement System

Indications for Use:

The Creaspine SupStance Vertebral Body Replacement System (SupStance VBR System) is a vertebral body replacement system intended to replace a vertebral body. The SupStance VBR System is designed for use in the thoracolumbar spine (T1- L5) to replace a collapsed, damaged, or unstable vertebral body during tumor or trauma (i.e., fracture) management procedures. The SupStance VBR System is intended to be used with supplemental internal fixation systems. Anterior thoracolumbar plates and screws or pedicle screw and rod systems are among the options for the surgeon to use.

The use of allograft and/or autograft with the SupStance VBR System is optional.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K072537